

EXHIBIT 3

Exhibit
in Re: Valsartan
Susan Bain
0002

Supplemental List of Documents Reviewed
January 29, 2023

Expert Reports

1. Expert Report of Ali Afnan, dated December 23, 2023
2. Amended Expert Report of Ali Afnan, dated January 11, 2023

ZHP Documents

1. PRINSTON0073443, Investigation regarding unknown impurity (genotoxic impurity) of Valsartan API (TEA process) (Version 2)
2. PRINSTON0076100, Investigation regarding unknown impurity (genotoxic impurity) of Valsartan API (TEA process)(Version 3)
3. PRINSTON00092999, August 22, 2014 Letter from FDA to Princeton Regarding ANDA 204821
4. PRINSTON00198071, ANDA for Valsartan and Hydrochlorothiazide Tablets, USP, 3.2.P.2 Pharmaceutical Development
5. ZHP01721348, Genotoxicity Statement, dated July 14, 2015
6. ZHP02600357, Genotoxicity Statement, dated July 14, 2015

Scientific Materials

- Juillard, J. Dimethylformamide: Purification, Tests For Purity And Physical Properties. Int'l Union of Pure and Applied Chem. Pergamon Press 1977
- Long, G., Meek, M.E. Concise International Chemical Assessment Document 31: N,N-Dimethylformamide. WHO 2001

Regulatory Documents

1. Food and Drug Administration, ANDAs: Impurities in Drug Substances (June 2009)
2. Food and Drug Administration, FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity (July 13, 2018)
3. Food and Drug Administration, FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings (Aug. 30, 2018)
4. Food and Drug Administration, FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues (Jan. 25, 2019)
5. USP, General Notices and Requirements (Apr. 1, 2015)

Deposition Testimony

1. Ramin (Ron) Najafi, Ph.D. Deposition Transcripts for January 18 and 24, 2023

2. Stephen S. Hecht, Ph.D. Deposition Transcripts for January 13, 2023, with all exhibits:

- Hecht-1 Letter Report of Stephen S. Hecht, PhD, dated July 6, 2021, No Bates Stamps, 44 Pages
- Hecht-2 Letter Report of Stephen S. Hecht, PhD, dated October 31, 2022, No Bates Stamps, 15 Pages
- Hecht-3 FDA Receipt Letter for ZHP Drug Master File Submission, Bates SOLCO00032578 through 32580
- Hecht-4 ZHP Product Development Report for Valsartan, Bates ZHP01710663 through 1710729
- Hecht-5 Amendment to Drug Master File dated April 16, 2012, Bates PRINSTON00079747 through 79755
- Hecht-6 Amendment to Drug Master File for Valsartan dated December 10, 2013, Bates PRINSTON00073102 through 73119
- Hecht-7 Expert Report of Fengtian Xue, PhD dated December 22, 2022, No Bates, 107 Pages
- Hecht-8 United States Patent 5,502,191 Issued March 26, 1996
- Hecht-9 FDA Statement entitled, "FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings" dated August 30, 2018, No Bates, Six Pages
- Hecht-10 FDA Statement entitled, "FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues," dated January 25, 2019, No Bates, Five Pages
- Hecht-11 Article entitled "High performance mini-gas chromatography-flame ionization detector system based on micro gas chromatography column," from Review of Scientific Instruments, published April 21, 2016
- Hecht-12 Email Chain ending 2/28/2019 in Chinese Language, Bates ZHP02630924 through 2630925
- Hecht-13 English Translation of Hecht-12, previously marked ZHP-265A
- Hecht-14 Document in Chinese Language previously marked ZHP-266, Bates ZHP02630926 through 2630927
- Hecht-15 English Translation of Hecht-14, Bates ZHP02630926 through 2630927
- Hecht-16 Email Chain ending December 27, 2016 Bates ZHP0477534 through 477553
- Hecht-17 Email Chain ending February 29, 2019, Bates ZHP02709940 through 2709984
- Hecht-18 Email Chain in Chinese Language ending February 28, 2019 previously marked ZHP-271, Bates ZHP00496153 through 496154

- Hecht-19 Document in Chinese Language previously marked ZHP-272, Bates ZHP00496155 through 496156
- Hecht-20 English Translation of Hecht-19, previously marked ZHP-272A
- Hecht-21 Email Chain ending December 22, 2016, Bates ZHP02118712 through 2118731
- Hecht-22 Email Chain ending April 20, 2017, Bates ZHP02118680 through 2118708
- Hecht-23 Chart titled "D5191-15-359," Bates ZHP02118709 through 2118711
- Hecht-24 Excerpt from Purification of Laboratory Chemicals, Fourth Edition, by W.L.F. Amarego and D.D. Perrin, No Bates, 21 Pages
- Hecht-25 Composite Exhibit, Copies of Dr. Hecht's Exhibit Binders
- Hecht-26 Curriculum Vitae of Stephen S. Hecht, PhD, Nine Pages 10
- Hecht-27 FDA Warning Letter 320-19-04 dated November 29, 2018, previously marked ZHP-213, Bates ZHP01344159 through 1344164
- Hecht-28 Article entitled "Identification and Control of Impurities for Drug Substance Development using LC/MS and GC/MS," from The Journal of Liquid Chromatography and Related Technologies
- Hecht-29 Document entitled "Valsartan, Analysis Report for Peak Identification in GC Chromatogram Other Than Listed Solvents," Bates ZHP01746277 through 1746288
- Hecht-30 Qualitative Reports, Bates SYNCOR00001458 through 1465
- Hecht-31 PowerPoint Presentation dated August 23, 2012, No Bates, 19 Slides